Appendix A – 510(k) SUMMARY

The 510(k) Summary is submitted in accordance with 21 CFR Part 807, Section 807.92. JUN - 4 2008

Submitter's Name:	Abbott Vascular
Submitter's Address:	3200 Lakeside Drive Santa Clara, CA 95054
Telephone:	951-914-2292
Fax:	951-914-1069
Contact Person:	Nadine Smith
Date Prepared:	May 19, 2005
Device Trade Name:	FoxCross PTA Catheter
Device Common Name:	PTA Catheter
Device Classification Name:	Catheter
Device Classification No.:	21 CFR 870.1250
Device Classification:	Class II
Device Product Code:	LIT

Device Description	The FoxCross PTA Catheter is a standard over-the-wire PTA catheter. The double lumen catheter has a balloon located near the distal tip. One lumen is used for inflation of the balloon, while the second lumen allows access to the distal tip of the catheter for guide wire insertion (max 0.035"). The balloon has two radiopaque markers for positioning the balloon relative to the stenosis. The balloon material expands to a known diameter at specific pressures.
Intended Use	The intended use for the device has not changed as a result of the modification. The FoxCross PTA Catheter is intended for dilatation of lesions in the femoral, renal, iliac, popliteal, peroneal, and profunda arteries and native or synthetic arteriovenous dialysis fistulae. This catheter is not intended for the expansion or delivery of stents.
Summary of Technological Characteristics Compared to Predicate Device	The FoxCross PTA Catheter, subject device, is identical in technological characteristics, to the FoxPlus PTA Catheter, predicate device, with respect to product code, classification section, classification name, intended use, catheter length, balloon diameters and lengths, introducer sheath size, and guide wire compatibility. Minor changes were to the FoxCross, including a different color for the shaft and tip, coating on the balloon, adhesive used, and removal of shrink tubing on the strain relief.
Summary of Substantial Equivalence	The FoxCross PTA Catheter, subject device, is substantially equivalent to the FoxPlus PTA Catheter, predicate device, as demonstrated by the results of the *in vitro* bench tests, analyses, and biocompatibility data.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 4 2008

Abbott Vascular
c/o Ms. Nadine Smith
Regulatory Affairs
26531 Ynez Road
Temecula, CA 92591

Re: K081417
FoxCross PTA Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II (two)
Product Code: LIT
Dated: May 19, 2008
Received: May 20, 2008

Dear Ms. Smith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Appendix A – Indications for Use

510(k) Number (if known) K081417

Device Name FoxCross PTA Catheter

Indications for Use The FoxCross PTA Catheter is intended for dilatation of lesions in the femoral, renal, iliac, popliteal, peroneal, and profunda arteries and native or synthetic arteriovenous dialysis fistula.

This catheter is not intended for the expansion or delivery of stents.

Prescription Use ____X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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Donna R. Vichnes

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ision of Cardiovascular Devices

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